

CLAIMS

1. A pharmaceutical composition comprising a pharmaceutically effective amount of (1S,2S)-1-(4-hydroxyphenyl)-2-(4-hydroxy-4-phenylpiperidin-1-yl)-1-propanol or a pharmaceutically acceptable salt thereof and water, wherein said composition contains less than about 2 parts per million of free copper ion and less than about 2 parts per million of free iron ion.
2. A pharmaceutical composition of claim 1, wherein said composition is substantially free of free copper ion and free iron ion.
3. A composition of claim 1, wherein said composition contains less than about 2 parts per million of any free trace metal ion.
4. A pharmaceutical composition of claim 3, wherein said composition is substantially free of any free trace metal ion.
5. A pharmaceutical composition of claim 1-4, further comprising a pharmaceutically acceptable buffer at a concentration effective to maintain the pH of the composition at between about 3.8 to about 5.0.
6. A pharmaceutical composition of claim 1-4, further comprising a pharmaceutically acceptable buffer at a concentration effective to maintain the pH of the composition at between about 4.0 to about 4.5.
7. A pharmaceutical composition of claim 1-4, further comprising a pharmaceutically acceptable buffer at a concentration effective to maintain the pH of the composition at between about 3.8 to about 5.0 wherein the anion of said buffer is selected from acetate, citrate, tartrate, formate and lactate.
8. A pharmaceutical composition of claim 1-4, further comprising a pharmaceutically acceptable buffer at a concentration effective to maintain the pH of the composition at between about 3.8 to about 5.0 wherein the anion of said buffer is lactate.
9. A pharmaceutical composition of claim 1-4, wherein said composition is substantially free of oxygen.
10. A pharmaceutical composition comprising (1S,2S)-1-(4-hydroxyphenyl)-2-(4-hydroxy-4-phenylpiperidin-1-yl)-1-propanol or a pharmaceutically acceptable salt thereof, water and a pharmaceutically

acceptable, chelating agent at a concentration effective to chelate with trace metal ions present in said composition.

11. A pharmaceutical composition of claim 10 wherein said chelating agent is selected from ethylenediaminetetraacetic acid, citric acid, 5 succinic acid and tartric acid and pharmaceutically acceptable salts thereof.

12. A pharmaceutical composition of claim 10, further comprising a pharmaceutically acceptable buffer at a concentration effective to maintain the pH of the composition at between about 3.8 to about 5.0.

13. A pharmaceutical composition of claim 12, wherein the anion of 10 said buffer is selected from acetate, citrate, tartrate, formate and lactate.

14. A pharmaceutical composition of claim 10, wherein said composition is substantially free of oxygen.

15. A pharmaceutical composition comprising (1S,2S)-1-(4-hydroxyphenyl)-2-(4-hydroxy-4-phenylpiperidin-1-yl)-1-propanol or a 15 pharmaceutically acceptable salt thereof in an aqueous solution, wherein the percent of the degradation product, 4-hydroxybenzaldehyde, is no more than about 0.15 percent of said composition following storage at 50°C for 12 weeks.

16. A pharmaceutical composition of claim 15, wherein the percent 20 of said degradation product is no more than about 0.07 percent.

17. The pharmaceutical composition of claim 16, wherein the percent of said degradation product is no more than about 0.04 percent.

18. A pharmaceutical composition comprising (1S,2S)-1-(4-hydroxyphenyl)-2-(4-hydroxy-4-phenylpiperidin-1-yl)-1-propanol or a 25 pharmaceutically acceptable salt thereof in an aqueous solution, wherein the percent of the degradation product, 4-hydroxy-4-phenylpiperidine, is no more than about 0.2 percent of said composition following storage at 50°C for 12 weeks.

19. A pharmaceutical composition of claim 18, wherein the percent 30 of said degradation product is no more than about 0.1 percent.

20. A pharmaceutical composition of claim 19, wherein the percent of said degradation product is no more than about 0.05 percent.

21. A method of preparing a pharmaceutical composition of (1S,2S)-1-(4-hydroxyphenyl)-2-(4-hydroxy-4-phenylpiperidin-1-yl)-1-propanol

comprising combining a pharmaceutically effective amount of (1S,2S)-1-(4-hydroxyphenyl)-2-(4-hydroxy-4-phenylpiperidin-1-yl)-1-propanol or a pharmaceutically acceptable salt thereof with a vehicle comprising water wherein said vehicle has been treated with a means to remove trace metal ions.

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22. A method of preparing a pharmaceutical composition of (1S,2S)-1-(4-hydroxyphenyl)-2-(4-hydroxy-4-phenylpiperidin-1-yl)-1-propanol comprising:

10 combining a pharmaceutically effective amount of (1S,2S)-1-(4-hydroxyphenyl)-2-(4-hydroxy-4-phenylpiperidin-1-yl)-1-propanol or a pharmaceutically acceptable salt thereof with a vehicle comprising water to form an aqueous solution; and

treating said aqueous solution with a means to remove trace metal ions.

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23. A method of treating stroke, spinal cord trauma, traumatic brain injury, multiinfarct dementia, CNS degenerative diseases such as Alzheimer's disease, senile dementia of the Alzheimer's type, Huntington's disease, Parkinson's disease, epilepsy, amyotrophic lateral sclerosis, pain, AIDS dementia, psychotic conditions, drug addictions, migraine, hypoglycemia, 20 anxiolytic conditions, urinary incontinence or an ischemic event arising from CNS surgery, open heart surgery or any procedure during which the function of the cardiovascular system is compromised, in a mammal, comprising administering to a mammal in need of such treatment a pharmaceutical composition of claim 1.

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